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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,612	07/26/2006	Patricia Denny	19644-005US1	6177

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
11/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,612	DENNY ET AL.	
	Examiner	Art Unit	
	LISA V. COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/14/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,15,16,26,29,48,49,54,55 and 57-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-9, 15, 16, 26, 29, 48, 49, 54, 55, and 57-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Vacated Abandonment

1. The notice of abandonment mailed 10/06/08 was issued inadvertently. The instant application is not abandoned. Accordingly the notice of abandonment is vacated. Examiner apologizes for any inconvenience this may have caused Applicant.

Amendment Entry

2. Applicant's response to the Office Action mailed 7/13/07 is acknowledged (paper filed 1/14/08). In the amendment filed therein claims 1, 3, 4, 6, 7, 8, 9, 15, 16, 29, 48, 49, 54, 55, 57, 58, 59, and 60 were modified. New claims 61-76 were added. Claims 5, 10-14, 17-25, 27-28, 30-47, 50-53, 56 were cancelled without prejudice or disclaimer. Currently claims 1-4, 6-9, 15-16, 26, 29, 48-49, 54-55, and 57-76 are pending and under consideration.

3. A species requirement was issued on 4/1/08. Applicant phoned Julie Burke to discuss the requirement. Mrs. Burke spoke with Spe Helms. Spe Larry Helms directed examiner Cook to withdraw the species election. Accordingly the requirement is withdrawn.

4. Objections and/or rejections of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-4, 9, 16, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345).

Seemann et al. disclose a method of evaluating high and low caries susceptibility in children. See abstract. Unstimulated saliva was allowed to accumulate in the oral cavity and the children were asked to spit out the saliva into a polypropylene sputum cup. Stimulated samples were also collected and measured. See page 157 –Collection of Saliva.

In the assay a salivary sample is simultaneously incubated with a purified biotinylated lectin on a microtiter plated precoated with a neoglycoprotein. Lectin binding to immobilized glycoproteins was quantified by the streptavidin-peroxidase detection system. See page 158 - 1st column and figure 1. The patient samples were measured in the microtiter assay (device with 1st matrix material) against control saliva samples of a known concentration (see baseline, 2 year caries, and salivary flow in Table 1 on page 159). The saliva of caries free subjects (CR) showed a higher binding inhibition against the PNA lectin that the saliva of children with DMFT greater than 4 (CS). See page 158 2nd column and Table 1.

Seeman et al. differ from the instant invention in not specifically teaching the measurement of two or more lectins.

However, Akintoye et al. teach methods to characterize salivary APP (lectin binding component) in caries-prone and caries-free individuals. Because APP interacts with S. mutans (the primary agent in the aetiology of dental caries), it was evaluated in dental caries and periodontitis. See page 338, 1st column, 3rd paragraph. Various lectins were utilized to determine partial glycosylation patterns of saliva samples. These lectins included BSA II, DSL, ECL, LEL, STL, and VVA. Of these lectins, Jacalin and LEL were found to be immunoreactive for APP. See column 340 section 2.11, Table 1, and paged 342 section 3.4. The researchers found that individual variability accounted for lectin differential binding. See page 343 2nd column.

It would have been prima facie obvious to one of ordinary skill in the art at the time of Applicant's invention to employ two or more lectins as taught by Akintoye et al. in the single lectin detection method of Seeman et al. because Akintoye et al. taught that various lectins bind differentially in individual samples. See page 343 2nd column. One of ordinary skill in the art would utilize multiple lectins in assay procedures in order to maximize the possibility of finding immunoreactivity. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Therefore one of ordinary skill in the art would have been motivated to evaluate multiple lectins in order to find the ones reactive with the specific individual samples analyzed.

II. Claims 49 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of Foster et al. (U.S. Patent#4,444,879).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) as set forth above.

Although Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations. In other words, the references fail to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example.

In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the assay reagents as taught by Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts which eliminate the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

III. Claims 15, 57-60, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of Shibuya et al. (US Patent #4,582,795).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) as set forth above.

Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) differ from the instant invention in not specifically teaching the measurement of a drop of saliva in a matrix material (device).

However, Shibuya et al. teach a method and device for the rapid diagnosis of dental caries. The device utilizes a very small amount of saliva (drop). See abstract and column 4 lines 38-40. This device makes saliva analysis simple, quick, and at a low cost. See column 5 lines 11-17.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ a device requiring only a drop of saliva as exemplified by Shibuya et al. with the dental caries detection method of Seemann et al. because Shibuya et al. taught that their device utilizes a very small amount of saliva (drop). See abstract and column 4 lines 38-40. Further making saliva analysis simple, quick, and inexpensive. See column 5 lines 11-17.

IV. Claims 6, 7, 8, 48, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of Sharon (1996, Adv Exp Med Biol, Vol408, pages 1-8).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) as set forth above.

Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) differ from the instant invention in not specifically all of the different known lectins as recited in the claims.

However, Sharon teaches that the carbohydrate lectin binding interaction is known and linked to various diseases. The various lectins can effect different species and used in disease treatment. See for example, page 1, Table 3, and Table 7. Absent evidence to the contrary the measurement of any one of the lectins known and taught by the prior art is deemed obvious.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ any of the known lectins in place of PNA, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

V. Claims 61-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of W.R. Hume (Journal of Dental Education, Vol.57, No.6, 6/1993, pages 439-443).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) as set forth above.

Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) differ from the instant invention in not specifically teaching disease risk levels and/or disease severity.

However, Hume teaches dental caries risk levels, assessment, and treatments. See pages 441-442 for example. Hume teaches that caries can be evaluated with multiple factors to determine whether the disease process begins, progresses, stops, or reverses. The use of this type of assessment increased understanding of the nature of the disease and has brought new ideas and productive challenges in both diagnosing and managing that will ultimately benefit dental caries patients. See page 442, 2nd column.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to assess caries disease risk levels as taught by Hume in the dental caries detection procedures of Seeman et al. in view of Akintoye et al. because Hume taught the use of risk level assessment increased understanding of the nature of the disease and has brought new ideas and productive challenges in both diagnosing and managing that will ultimately benefit dental caries patients. See page 442, 2nd column.

VI. Claims 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of Shibuya et al. (US Patent #4,582,795) as applied to claims 15, 57-60, and 69 above, and further in view of Lindmo (U.S.Patent #5,585,241).

Please see Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of Shibuya et al. (US Patent #4,582,795) as set forth above.

However, Lindmo disclose a flow cytometry method of detecting analytes via microbeads (particles). The microbeads are coupled to reactants (specific binding partners) wherein the analyte and the reactant include a wide range of binding partners. These binding partners are taught to include enzymes, enzyme cofactors, hapten, and antihaptens. The separation between the bound and non-bound reagents is not required. (See column 5, line 7-12).

Lindmo also discloses the utility of predetermined amount of microbeads with predetermined amount of labeled reactants with specific affinity for the analyte in question. Specifically, Lindmo employs different particle sizes and carrying reactants with the same specificities but different binding affinity for the analyte (see abstract).

Lindmo teaches that if the high and low affinity reactants are coated separately onto particles of different types which can be distinguished in flow cytometry, the amounts of the analytes by the high affinity and low affinity reactants may be independently and simultaneously measured in the same sample (column 3, lines 22-53). Where more than one analyte is to be assayed, pairs of particle types will be used such that the signals from the particle types can be distinguishable (column 4, lines 34-40). Different labels may be used to detect each analyte as well as differing bead size. The pairs of microbead types may be the same for each analyte while the qualitative different is exhibited in the signal from each label, i.e. fluorescence wavelength, will distinguish the respective particle population (column 4, lines 51-55). Lindmo further, teaches application of the method in variations of assays such as sandwich and competitive immunoassay. Lindmo's teachings make it possible to obtain high sensitivity while increasing the measurement range and precision of the method.

Lindmo teaches the incubation of each group of particles individually to determine individual analysis of each particle. See column 6 and figures 5, 7A, and 7B. The groups of particles are incubated with labeled binding members, Lindmo teaches this in columns 4-5.

Specifically the assayed monodisperse particles carrying a specific binding partner for the analyte of interest is contacted with a labeled ligand. See column 4 lines 5-21. The labeled ligand may be added to the sample mixture before or after the particles or simultaneously therewith. Column 5 lines 25-26.

One of ordinary skill in the art at the time the invention was made would have included the different sized particles (a selected differential parameter) of Lindmo in the method of Seemann et al. (Caries Research, 2001, Vol.35, pages 156-161) in view of Akintoye et al. (Archives of Oral Biology, Vol.47, 2002, pages 337-345) and further in view of Shibuya et al. (US Patent #4,582,795) because Lindmo taught that the different sized particles allowed for multiple analyte analyses. Column 4, lines 34-40.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to employ various configured particles/beads to obtain high sensitivity while increasing the measurement range and precision of the method.

Response to Arguments

Applicant's arguments and amendment have been carefully considered and found persuasive. Accordingly new rejections have been presented herein.

15. For reasons aforementioned, no claims are allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Lisa V. Cook/
Examiner, Art Unit 1641